### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

In re: Valsartan Products Liability Litigation

MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

### **DECLARATION OF THOMAS S. MOFFATT**

- I, Thomas S. Moffatt, being competent and over the age of twenty-one (21), state that I have personal knowledge of the following facts and hereby declare under penalty of perjury:
- 1. I am authorized to provide this declaration on behalf of CVS Pharmacy, Inc. ("CVS").
- 2. I have worked at CVS for nearly twenty-five years, and I am currently employed as Vice President, Assistant Secretary and Senior Legal Counsel Corporate Services of CVS. In that capacity, I am generally familiar with CVS's overall business operations, including its acquisitions and business purchases.
- 3. In late 2018, CVS entered into an agreement with Quick Chek Corporation to acquire assets pertaining to ten (10) of Quick Chek's pharmacies in New Jersey. Pursuant to the Asset Purchase Agreement ("Agreement"), CVS purchased certain fixed assets for one of the pharmacies and intended to operate a pharmacy at that "store buy" location following development of the site.
- 4. Pursuant to the Agreement, the remaining nine Quick Chek stores, including Store #39 in Passaic, New Jersey, were designated as "file buy" locations. For these nine "file buy"

locations, Quick Chek intended to continue to operate convenience stores at those locations, but the pharmacy within the store would close.

- 5. Pursuant to the Agreement, CVS purchased certain pharmacy inventory, customer lists and related history, and prescription files. CVS also agreed to make the protected health information that was part of Quick Chek's pharmacy data available for access to patients.
- 6. For the "file buy" locations, including Store #39 in Passaic, New Jersey, CVS did not acquire the store itself or the lease/pharmacy space, did not continue to employ its employees, and did not continue to operate a pharmacy.
- 7. CVS did not assume any liability relating to Quick Chek's pharmacy operations. The Agreement provides in relevant part that CVS "shall not assume, or be obligated to perform, pay, or otherwise discharge, any liability or obligation of [Quick Chek] of any nature whatsoever, including, without limitation, any type of successor liability, as a result of the transactions contemplated" within the agreement, except for certain limited lease obligations related to the "store buy" location. Furthermore, Quick Chek "expressly acknowledges and agrees that [CVS] is not assuming, and [Quick Chek] expressly disclaims and declines assumption of any and all obligations and/or liabilities of [Quick Chek] or otherwise relating to the Pharmacies."

Executed March 29, 2022 at Woonsocket, Rhode Island.

Thomas S. Moffatt



August 2018

#### URGENT PRODUCT RECALL INFORMATION

Dear Walgreens Prescription Patient,

Our records indicate that you received one or more prescriptions for the following product(s) listed below from a Walgreens pharmacy.

#### Recalled Product Information

| Product Name                       | Description       | NDC           |
|------------------------------------|-------------------|---------------|
| Amlodipine/Valsartan/ HCTZ Tablets | 10mg/320mg/25mg   | 13668-0325-30 |
| Amlodipine/Valsartan/ HCTZ Tablets | 10mg/160mg/25mg   | 13668-0328-30 |
| Amlodipine/Valsartan/ HCTZ Tablets | 10mg/160mg/12.5mg | 13668-0327-30 |
| Amlodipine/Valsartan/ HCTZ Tablets | 5mg/160mg/12.5mg  | 13668-0326-30 |
| Amlodipine/Valsartan/ HCTZ Tablets | 5mg/160mg/25mg    | 13668-0329-30 |
| Amlodipine/Valsartan Tablets       | 5mg/160mg         | 13668-0207-30 |
| Amlodipine/Valsartan Tablets       | 10mg/160mg        | 13668-0206-30 |
| Amlodipine/Valsartan Tablets       | 10mg/320mg        | 13668-0204-30 |
| Amlodipine/Valsartan Tablets       | 5mg/320mg         | 13668-0205-30 |

Torrent Pharmaceuticals Limited is voluntarily recalling these items due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

Patients who are on valsartan should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Please contact your physician to discuss an alternative treatment plan as valsartan containing products may not be available in the near future.

To arrange for a refund of unused medication, please contact Torrent's returns company, Qualanex at 1-800-505-9291 (8:00 am-5:30 pm Eastern Time). Qualanex will send you pre-paid shipping materials. Please include the recalled medication and a copy of your receipt and you will be issued a refund by Torrent. Please do not return the recalled product back to Walgreens, as this number has been established to ensure patient support.

If you have any medical questions regarding this recall, please contact Torrent Pharma Inc. at 1-800-912-9561 (8:00 am - 5:00 pm Eastern Time).

Thank you for your prompt attention to this matter. We look forward to seeing you at Walgreens for all of your healthcare needs.

Richard M. Ashworth, R.Ph. President of Operations

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Email:sales@huahaipharm.com http://www.huahaipharm.com

### NOTIFICATION

August 3, 2018

Re: Valsartan API / NDMA

To whom it may concern,

Please note that based on our further assessment, the trace amount of NDMA is detected in Valsartan API manufactured with the Old Process using Triethylamine Hydrochloride (TEA) as reagent. Therefore, you are requested to put on hold the use of the API and take necessary actions about the formulation made with the API.

(Jenson YE, Quality VP)

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.



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#### NOTIFICATION

September 14, 2018

Re: NDEA Containment in ValsartanAPI (TEA Process)

To whom it may concern,

Following our notification regarding Valsartan on Auguest 3<sup>rd</sup>2018, a new genotoxic impurity N-nitrosodiethylamine (NDEA) was detected in Valsartan TEA process during our recent investigation.

We are now in full speed on further investigation and will keep you updated.

Ms. Baozhen Chen Director, Quality

Zhejiang Huahai Pharmaceutical Co., Ltd.





Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Valsartan/Amlodipine/HCTZ
Tablets

Contact
Torrent Medical Information
1-800-912-9561
Medinfo.Torrent@apcerls.com

**FOR IMMEDIATE RELEASE – August 17, 2018–**Torrent Pharmaceuticals Limited is voluntarily recalling 14 lots of Valsartan/Amlodipine/HCTZ tablets to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Valsartan is used to control high blood pressure and for the treatment of heart failure. In combination with amlodipine plus hydrochlorothiazide, it is used to control high blood pressure. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

| NDC              | Product Description   | Lot/Batch | Expiration<br>Date |
|------------------|---|-----------|--------------------|
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets    | BBX2D025  | Nov-2019           |
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 10mg/320mg/25mg, 30 Tablets | BBX2D026  | Nov-2019           |
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 10mg/320mg/25mg, 30 Tablets | BBX2E001  | Jan-2020           |
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets    | BBX2E002  | Jan-2020           |
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets    | BBX2E003  | Jan-2020           |
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 10mg/320mg/25mg, 30 Tablets | BBX2E004  | Jan-2020           |

| NDC              | Product Description  | Lot/Batch | Expiration<br>Date |
|------------------|--|-----------|--------------------|
| NDC 13668-325-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets     | BBX2E005  | Jan-2020           |
| NDC 13668-328-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets     | BBX9D004  | Nov-2019           |
| NDC 13668-328-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 10mg/160mg/25mg, 30 Tablets  | BBX9E001  | Jan-2020           |
| NDC 13668-326-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 5mg/160mg/12.5mg, 30 Tablets | BBY1E001  | Dec-2019           |
| NDC 13668-326-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 5mg/160mg/12.5mg, 30 Tablets | BBY1E003  | Mar-2020           |
| NDC 13668-327-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/12.5mg, 30 Tablets   | BBY2E001  | Mar-2020           |
| NDC 13668-329-30 | Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets      | BBY4D004  | Nov-2019           |
| NDC 13668-329-30 | Amlodipine, Valsartan and Hydrochlorothiazide<br>Tablets, USP 5mg/160mg/25mg, 30 Tablets   | BBY4E001  | Jan-2020           |

Valsartan/Amlodipine/HCTZ tablets were distributed Nationwide to Torrent's wholesale, distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Torrent Pharmaceuticals Limited at:

- \* 1-800-912-9561 (live calls received 8:00 am 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week).
- \* Medinfo.Torrent@apcerls.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

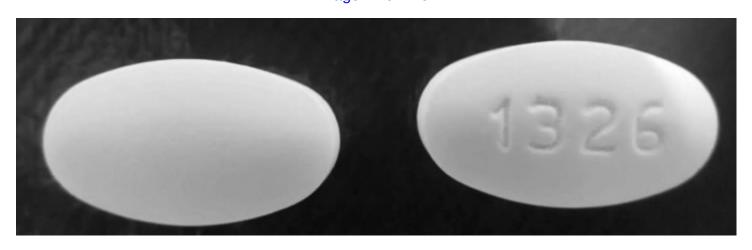
Any general **questions regarding the return of this product** please contact Qualanex at 1-800-505-9291 (live calls received 8 am -5:30 pm Eastern Time).

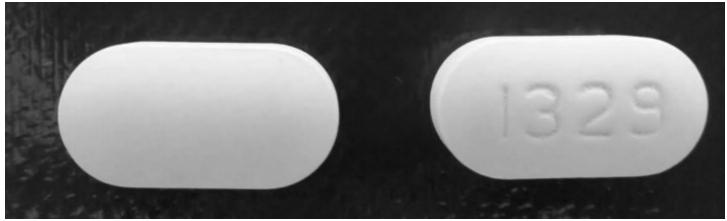
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

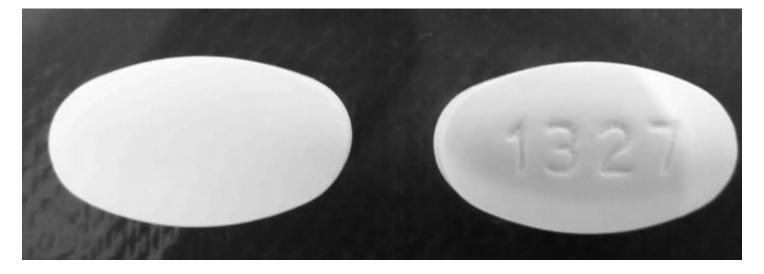
Complete and submit the report **Online**: <a href="www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm

Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

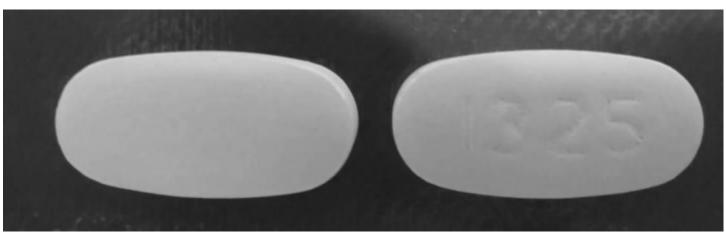
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

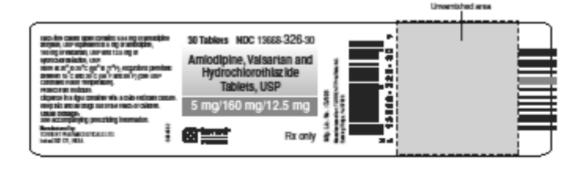




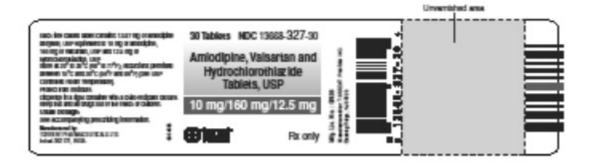


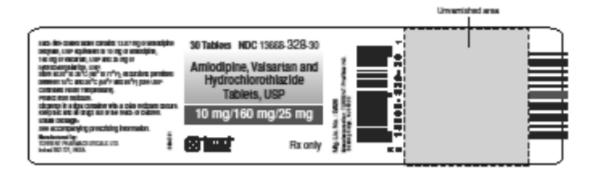


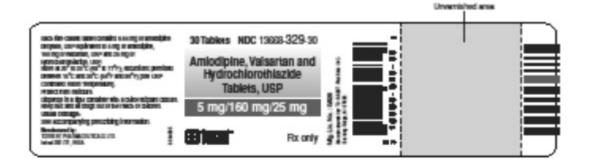




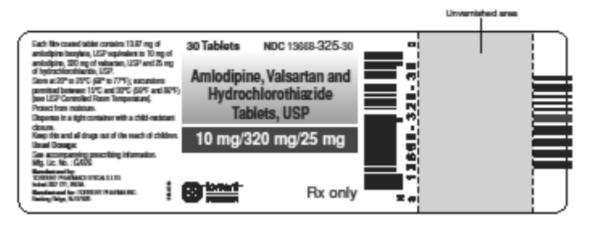
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#### NOTIFICATION

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June 20, 2018

Re: Valsartan API

To whom it may concern,

Recently, we came to be aware of a previously unknown impurity that may have genotoxic potential.

We request you to put temporarily on hold the use of Valsartan API immediately.

We will keep you posted for any further progress.

(Jenson YE, Quality VP)

ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD.